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Search results from the "OB_Rx" table for query on "021196."

Active Ingredient:	SODIUM OXYBATE
Dosage Form;Route:	SOLUTION;ORAL
Proprietary Name:	XYREM
Applicant:	JAZZ PHARMS
Strength:	500MG/ML
Application Number:	N021196
Product Number:	001
Approval Date:	Jul 17, 2002
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	

Patent and Exclusivity Info for this product: [View](#)[Return to Electronic Orange Book Home Page](#)⁶

FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

Division of Labeling and Program Support

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Orange Book Data Updated Through April 2014

Patent and Generic Drug Product Data Last Updated June 11, 2014

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U.S. Food and Drug Administration

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
 Patent and Exclusivity Search Results from query on Appl No 021196 Product 001 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N021196	001	6780889	Jul 4, 2020		Y		
N021196	001	7262219	Jul 4, 2020		Y		
N021196	001	7668730	Jun 16, 2024			U - 1110	
N021196	001	7765106	Jun 16, 2024			U - 1069	
N021196	001	7765107	Jun 16, 2024			U - 1070	
N021196	001	7851506	Dec 22, 2019			U - 1101	
N021196	001	7851506	Dec 22, 2019			U - 1102	
N021196	001	7895059	Dec 17, 2022			U - 1110	
N021196	001	8263650	Dec 22, 2019		Y	U - 1101	
N021196	001	8263650	Dec 22, 2019		Y	U - 1102	
N021196	001	8324275	Dec 22, 2019			U - 1101	
N021196	001	8324275	Dec 22, 2019			U - 1102	
N021196	001	8457988	Dec 17, 2022			U - 1110	
N021196	001	8589182	Dec 17, 2022			U - 1110	
N021196	001	8731963	Dec 17, 2022			U - 1110	

Exclusivity Data

There is no unexpired exclusivity for this product.

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
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